Stago

K 093001

CONFIDENTIAL

Attachment - 6

DEC 18 2009

510 (k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Umberto V. Parrotta
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Phone: (973) 631-1200, x-2044
Facsimile: (973) 695-0095

Contact Person: Umberto V. Parrotta

Data Prepared: September 25, 2009

Name of Modified Device and Name/Address of Sponsor:

STA-R Evolution® Expert Series Hemostasis System or STA-R Evolution® Expert Series.

Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Common or Usual Name:

- IVD Coagulation Device/Instrument.
- Automated and Semi-Automated Hematology Device.
- Multi-Parametric Analyzer

Classification Name:

System, Multipurpose for In Vitro Coagulation Studies

Predicate Device:

Diagnostica Stago's STA-R Evolution® Expert Series Automated Multi-Parametric Analyzer (K082675).

Purpose of the Special 510(k) Notice:

The STA-R Evolution® Expert Series Hemostasis System is a modification to the company's own legally marketed device, STA-R Evolution® Expert Series (K082675).

The modification of the device involves replacement of components for reliability or obsolescence reasons, changes in the device application software to provide

operator/user use enhancements and modification of the data post-processing to increase results reliability and bug corrections. Additionally, to increase reliability of results, a new option (*Reverse Sequence Drilling Mode* referred to as PTB) is proposed when using capped tubes (involves software revision and mechanical changes).

Indication/Intended Use:

The STA-R Evolution® Expert Series Hemostasis System is a fully automatic clinical instrument designed to perform tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

Principles of Operation:

The STA-R Evolution® Expert Series Hemostasis System is designed as a fully automatic system. Samples and test reagents are loaded into the instrument where sample handling, reagent delivery, analysis, and reporting of results are performed automatically. A central processing unit controls instrument functions such as, management of patient results, quality control, support for instrument maintenance, and work load optimization.

The instrument utilizes Diagnostica Stago reagents in addition to open adaptation of other currently available reagents. Barcoding of test reagents, calibrators, and controls facilitate their use on the system and permits reagent management simple. Manual entry of reagent information enables the use of non-barcoded reagents.
The instrument performs multiple test methodologies in random access as selected by the user. These include clotting time or clot-based tests (i.e. chronometric) measurements and photometric assays (at specific wavelengths) on plasma samples.

STA-R Evolution® Expert Series Hemostasis System is the modified version of the Company's STA-R Evolution® Expert Series (K082675), legally marketed predicate device. The modification of the device involves replacement of components for reliability or obsolescence reasons, changes in the device application software to provide operator/user use enhancements, modification of the data post-processing to increase results reliability and bug corrections. In addition, also to increase results reliability, a new option is proposed when using capped tubes.

Principles of Operation for the aforementioned analyses are the same between the subject submission device and the Predicate Device.

Substantial Equivalence:

STA-R Evolution® Expert Series Hemostasis System and its Predicate Device, STA-R Evolution® Expert Series (K082675) have the same Indications for Use, Technology, Principles of Operation and comparable Performances. The technical characteristics have been modified thus, resulting in better performance, without any change in technology or principle of operation.

The modifications consist in new hardware and mechanical components to increase the operation reliability or to replace obsolete components. The software was updated to

include operator/user use enhancements, modification of the data post-processing to increase results reliability, and bug corrections. Additionally, to increase results reliability, a new option of Reverse Sequence Drilling Mode {referred to as PTB) (applicable when the plasma volume used in tests on the analyzers is less than 12µl) is implemented when using capped tubes.

Nevertheless, there are no new questions regarding the Safety, Effectiveness, Technology, Principles of Operation and Performance as evidenced by Risk Assessment and Validation Studies (including all the changes mentioned above. Therefore, the STA-R Evolution® Expert Series Hemostasis System is substantially equivalent to the STA-R Evolution ® Expert Series (K082675), predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

DEC 18 2009

Diagnostica Stago, Inc.
c/o Umberto V. Parrotta
Director of Regulatory Affairs and Quality Assurance
5 Century Drive
Parsippany, NJ 07054

Re: k093001
Trade/Device Name: STA-R Evolution® Expert Series Hemostasis System
Regulation Number: 21 CFR §864.5425
Regulation Name: System, multipurpose for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: December 8, 2009
Received: December 10, 2009

Dear Umberto V. Parrotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Stago

Attachment – 2A **CONFIDENTIAL**

DEC 1 8 2009

Indications for Use

510(k) Number (if known): K093001

Device Name:

STA-R Evolution® Expert Series Hemostasis System

Indications for Use:

STA-R Evolution® Expert Series Hemostasis System is a fully automatic clinical instrument designed to perform tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K093001